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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/809,197 | 03/16/2001 | Yusuke Amino | 203348US0CONT | 6248 |
| 22850 | 7590 | 01/27/2006 | EXAMINER | |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | OH, TAYLOR V | |
| | | | ART UNIT | PAPER NUMBER |

1625

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/809,197 | Applicant(s) AMINO ET AL. | |
| | Examiner Taylor Victor Oh | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11,12/03&5/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/5/03 has been entered.

The Status of Claims

Claims 1-62 are pending.

Claims 1-62 have been rejected.

DETAILED ACTION

1. Claims 1-62 are under consideration in this Office Action.

Priority

2. It is noted that this application is a continuation of PCT/JP99/04977 filed on 09/10/1999; the foreign priority documents, JP 11-169419 (06/16/1999) and JP 10-264252 (09/18/1998) are in the file.

Drawings

3. None.

Claim Objections

Claim 1 is objected to because of the following informalities:

Claim 1 has contained the negative proviso in the followings:

where R₆, R₇, R₈, R₉ and R₁₀ are hydrogen atoms at the same time,

where R₆ is a methyl group, R₁, R₂, R₃, R₄, R₅, R₇, R₈, R₉, R₁₀ and R₁₂ are a hydrogen atom at the same time and R₁₁ is a benzyl group or a p-hydroxy benzyl group, at the same time; and

where R₂ or R₄ is a methoxy group, R₃ is a hydroxyl group, R₁₀ is a methyl group, R₁, R₄ or R₂, R₅, R₆, R₇, R₈ and R₉ are hydrogen atoms at the same time, and R₁₁ is a benzyl group or a p-hydroxy benzyl group.

However, the limitations with the negative proviso are not present and shown in the original specification. A close inspection of the original claims and specification do not provide antecedent basis for the proposed changes. New matter can not be introduced into specification at any time during the prosecution, unless there is a supporting description that would support the proposed changes. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Art Unit: 1625

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has contained the negative proviso in the followings:

where R₆, R₇, R₈, R₉ and R₁₀ are hydrogen atoms at the same time,

where R₆ is a methyl group, R₁, R₂, R₃, R₄, R₅, R₇, R₈, R₉, R₁₀ and R₁₂ are a hydrogen atom at the same time and R₁₁ is a benzyl group or a p-hydroxy benzyl group, at the same time; and

where R₂ or R₄ is a methoxy group, R₃ is a hydroxyl group, R₁₀ is a methyl group, R₁, R₄ or R₂, R₅, R₆, R₇, R₈ and R₉ are hydrogen atoms at the same time, and R₁₁ is a benzyl group or a p-hydroxy benzyl group.

However, the negative proviso with these groups lacks description in the original specification (see page 5-7). Therefore, the addition of the negative proviso with these groups to the claims does not provide antecedent basis for the proposed changes. New matter can not be introduced into specification at any time during the prosecution, unless there is a supporting description that would support the proposed changes.

Art Unit: 1625

Applicant is required to cancel the new matter in the reply to this Office Action. The proviso lacks description. Even a negative limitation requires description, *Ex Parte Grasselli*, 231 USPQ 393.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

In claims 33 and 34, the phrase "a substituent which can be converted into a hydrogen atom." is recited. This is vague and indefinite because there is no step for how the substituent is converted into hydrogen. The omitted step is: the reductive alkylation is conducted in the presence of $\text{NaB(OAC)}_3\text{H}$ at 0°C and at room temperature. Therefore, an appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

Art Unit: 1625

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

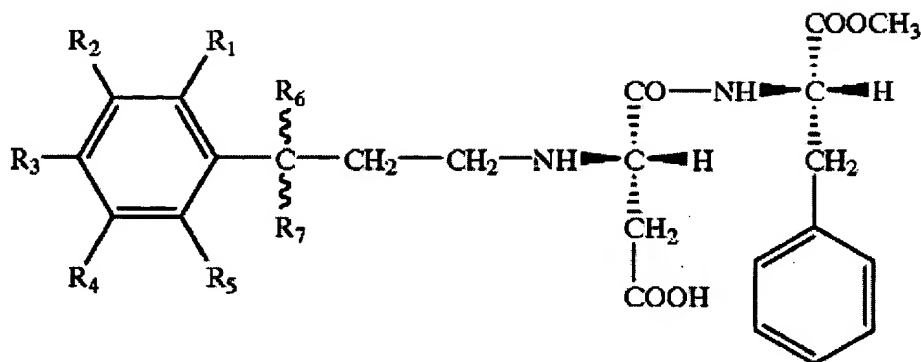
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 9, 12, 14, 16, 18-20, 24-25, 29-31, 33-34, 37, 43, 46, 48, 50, and 58 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 19-28 of U.S. Patent No. 6,649,784 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention embraces another conflicting application based on the ground of the genus versus species relationship.

U.S. Patent No. 6,649,784 B2 discloses an aspartyl dipeptide ester derivative represented in the following formula (1):

Art Unit: 1625



wherein R₁, R₂, R₃, R₄ and R₅, independently from each other, represent a hydrogen atom or a hydroxyl group, at least any two of R₁ to R₅ are hydroxyl groups, and R₆ and R₇, independently from each other, represent a hydrogen atom or an alkyl group having 1 to 3 carbon atoms.

as well as a method for making a compound of formula (1) comprising:

reductively alkylating aspartame with a
3-phenylpropionaldehyde or cinnamaldehyde
derivative and a reducing agent.

The difference between claims 1, 31, and 33-34 of the instant invention and claims 1 and 28 of U.S. Patent No. 6,649,784 B2 is the broadness of the genus of the claimed compound in comparison with small set of species in the U.S. Patent No. 6,649,784 B2.

Even so, their inventive subject matters are same with respect to the claimed N-alkylaspartyl dipeptide ester compound and its method of making the claimed compound. The rest of the dependent claims are variations of each other regarding the emphasis of the particular groups of the instant invention and some of the claims

Art Unit: 1625

between two applications are regrouped together. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to rearrange the claims in order to accentuate the particular part of the claimed invention. This is because the skilled artisan in the art would expect such a rearrangement to be successful since their inventive subject matters are embraced with each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Taylor V Oh
1/13/06